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Health Literacy

The influence of health literacy level on an educational intervention to improve glaucoma medication adherence

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ABSTRACT

Objective: To test an educational intervention targeted to health literacy level with the goal of improving glaucoma medication adherence.
Methods: One hundred and twenty-seven veterans with glaucoma were randomized to glaucoma education or standard care. The intervention included a video scripted at a 4th, 7th, or 10th grade level, depending on the subject's literacy level. After six months, the number of days without glaucoma medicine (DWM) according to pharmacy records for the intervention and control groups was compared.
Results: The number of DWM in the six months following enrollment was similar for control and intervention groups (intervention, $n = 67$, DWM = 63 ± 198; standard care, $n = 60$, DWM = 65 ± 198; $p = 0.708$). For each subgroup of literacy (adequate, marginal, inadequate), subjects in the intervention group experienced less mean DWM than subjects in the control group and the effect size (ES) increased as literacy decreased: adequate literacy, ES 0.069; marginal, ES 0.183, inadequate, ES 0.363. Decreasing health literacy skills were associated with decreasing self-reported satisfaction with care (slope = 0.017, SE = 0.005, $p = 0.002$).
Conclusions: Patients with decreased health literacy skills may benefit from educational efforts tailored to address their health literacy level and learning style.
Practice implications: Providers should consider health literacy skills when engaging in glaucoma education.

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1. Introduction

Glaucoma is the leading cause of irreversible blindness worldwide [1,2] and disproportionately affects older adults and African-Americans in both prevalence and severity [3–5]. The number of Americans with glaucoma is expected to increase by 50% in the next 15 years [3]. Multiple studies have shown that with effective medical treatment, much glaucomatous vision loss can be prevented through reduction in intraocular pressure (IOP) [6–9]. Despite this, glaucoma medications often are not instilled as prescribed [10–14]. Multiple factors contribute to glaucoma medication nonadherence, including patients' lack of understanding of the potentially blinding nature of the disease [15,16], and poor health literacy [17,18].

Health literacy is defined by the Institute of Medicine as "the degree to which individuals have the capacity to obtain, process, and understand basic information and services needed to make appropriate decisions regarding their health [19]." The 2003 National Assessment of Adult Literacy revealed that more than 75 million adults in the United States possess only basic or less than basic health literacy skills [20]. Poor health literacy skills are associated with increased rates of hospitalization [21], less use of preventive services [22], and increased overall mortality [23].

In two separate studies, it was found that around 50% of adults with open angle glaucoma possess poor health literacy skills [17,18]. Not only may decreased health literacy skills be associated with decreased adherence to the prescribed glaucoma medication regimen [17], but patients with lower literacy skills demonstrate more advanced visual field loss than their more literate peers [18].

Although the mechanisms connecting health literacy and outcomes in glaucoma management are not clear, work in other chronic diseases such as diabetes and hypertension suggest that poor disease knowledge and self-management skills may play an intermediary role [24]. In a group of patients with poorly controlled

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diabetes, an educational intervention targeted to the individual's health literacy level resulted in improved diabetes control in those subjects with poor health literacy skills [25]. Recently, in the eye care community, greater attention has been paid to the issue of limited health literacy, but most ophthalmic patient educational materials are more appropriate for those patients with more advanced literacy skills [26]. Although more than 10 percent of glaucoma patients scored in the lowest literacy category on a standardized assessment of health literacy [17], to our knowledge, no patient educational materials are publicly available for those glaucoma patients functioning at less than a sixth grade reading level [27]. The purpose of this study was to compare the effectiveness of an educational intervention targeted to an individual's health literacy level to routine care in improving glaucoma medication adherence.

2. Methods

The study is a randomized controlled trial in which patients of the Durham Veterans' Affairs Medical Center with medically treated glaucoma were eligible to participate. Institutional Review Board approval was obtained and the study was performed in accordance with HIPAA regulations. Subjects were excluded if their best-corrected visual acuity in the better seeing eye was less than 20/200, as low vision would interfere with literacy assessment. Subjects who provided informed consent were administered the Mini Mental State Exam [28] (MMSE) to assess cognitive function, the Test of Functional Health Literacy in Adults [29] (ToFHLA) and a brief survey assessing presence of a comorbidity affecting ability to instill eye drops (yes/no), self-reported disease knowledge and satisfaction with care (Likert scales). All individuals were required to have 18 or higher on the MMSE as significant cognitive dysfunction would confound the response to the educational intervention. The protocol also excluded subjects who had eye surgery in the past month, as ocular medication may change frequently in the post-operative period.

Subjects were randomized in a one-to-one fashion to standard care or an educational intervention. Standard care involved usual management by the treating ophthalmologist, including any glaucoma education which he or she might provide. The educational intervention involved a one-on-one session with the study coordinator, lasting approximately 20 min. The study coordinator, with a background in ophthalmic research but not clinical ophthalmology, was trained by an ophthalmologist on the content and delivery of the intervention. A sample of interventions was observed by a glaucoma subspecialist to ensure quality and consistency. All subjects in the educational intervention group were shown an informational video about glaucoma, but the language of the video varied according to the subjects' tested health literacy level. Subjects who scored less than 60 on the ToFHLA, indicating inadequate health literacy skills, saw a video scripted at a fourth grade reading level. Subjects who scored 60–74 on the ToFHLA, indicating marginal health literacy, saw a video scripted at a seventh grade reading level. Subjects who scored greater than 74 on the health literacy assessment, saw a video scripted at a tenth grade reading level. A glaucoma subspecialist created the scripts and evaluated the content according to the Flesch-Kincaid Grade Level assessment in Microsoft Word. In 2–5 min, all three videos used imagery to explain the anatomy of the eye including the structures involved in glaucoma and examples of glaucomatous vision loss. Drop instillation techniques were demonstrated. Subjects in the inadequate and marginal literacy groups were also shown diagrams of the eye as the study coordinator reviewed the educational information. Subjects who scored in the adequate health literacy level were given the American Academy of Ophthalmology educational brochure about glaucoma, written at a 10th grade reading level.

All subjects in the intervention group were also taught how to instill eye drops and asked to demonstrate proper drop instillation technique for the study coordinator. All subjects in the intervention group received a phone call once a month asking if he or she were having any problems with the medication.

The medical record was reviewed to collect demographic information such as age, gender, self-reported race, glaucoma-related diagnosis, and prescribed medications, including unilateral or bilateral administration and prescribed frequency of dosing. The VA pharmacy records were reviewed to determine the number and frequency of requested glaucoma medication refills over the six months following enrollment.

2.1. Statistical methods

The primary outcome measure of this study was the number of days without medication (DWM; the difference between the number of days medication was available to the subject according to the pharmacy records and the prescribed dosing and the number of days that medication was required over the study period). The number of drops available per bottle was derived from a previously published study which specified drops according to medication, bottle size, and manufacturer [10]. If a subject was prescribed more than one glaucoma medication, the number of DWM for each medication was summed. If the pharmacy records indicated a surplus of medication, the surplus was considered equivalent to an adequate supply of medicine (i.e., for a subject with a surplus of one medication and an inadequate supply of a second medication, the total DWM would reflect only the inadequate supply).

Secondary outcome measures included medication possession ratio (MPR), defined as the ratio of the number of days that the medication was available to the number of days that medication was required over the study period. The MPR is derived from the same data as DWM and, as such, is closely related. Both DWM and MPR were calculated because both measures are commonly reported in adherence literature. Presence of comorbid disability, self-reported disease knowledge, and satisfaction with care were also assessed as outcomes in regards to measured health literacy level.

First, descriptive statistics were obtained including mean, median and standard deviation. Continuous outcomes and predictors were analyzed with linear regression and continuous outcomes with dichotomous predictors were analyzed with the unpaired Student's *t*-test. An alpha level of 0.05 was used to determine statistical significance.

3. Results

Between September 27th, 2007 and November 18th, 2008, 131 patients of the Durham VA Medical Center Eye Clinic met enrollment criteria and provided informed consent to participate in the study. Two subjects withdrew and two subjects were subsequently excluded because they were not prescribed glaucoma medication during the course of the study or they had recent intraocular surgery. No subjects were excluded due to inadequate score on the MMSE. Of the 127 subjects who completed the study, all but one were men, ranging in age from 43 to 87 years. Characteristics of the study participants are described in Table 1.

3.1. Medication adherence

After comparing days that medication was available according to the pharmacy refill records to the number of days that medicine was required, we found that 72 of the 127 subjects (57%) experienced DWM over the six months following enrollment. The number of DWM ranged from one week to 549 days (for a subject without three prescribed medications for six months); mean

Table 1
Characteristics of subjects.

	Total Number (%)	Intervention Number (%)	Control Number (%)
Number of subjects	127	67 (53)	60 (47)
Gender			
Male	126 (99)	67 (100)	59 (99)
Female	1 (1)		1 (1)
Race			
Caucasian	37 (29)	17 (25)	20 (33)
African American	89 (70)	49 74)	40 (64)
Other	1 (1)	1 (1)	
Age (years)	Mean 66 (SD 9.6)	Mean 66 (SD 9.2)	Mean 66 (SD 10.1)
Glaucoma-related diagnosis			
• Primary open angle glaucoma	68 (53)	40 (60)	28 (46)
• Open angle glaucoma not otherwise specified	39 (31)	21 (31)	18 (30)
• Normal tension glaucoma	9 (7)	3 (4)	6 (10)
• Pigment dispersion glaucoma	1 (1)	0	1 (2)
• Combined mechanism glaucoma	2 (2)	1 (1)	1 (2)
• Glaucoma suspect	8 (6)	2 (3)	6 (10)
Glaucoma medication prescribed for both eyes	112 (88)	57 (85)	55 (92)
Prescribed more than one glaucoma medication	82 (65)	44 (66)	38 (63)

Table 2
Days without medicine in the six months following enrollment according to literacy level and treatment group.

Health literacy	Treatment group	No. subjects	Days without medication mean (SD)	*p*-Value	Effect size[a]
Inadequate	Standard	13	92 (113	0.173	0.363
	Intervention	13	51 (83)		
Marginal	Standard	12	124 (213)	0.679	0.183
	Intervention	8	85 (120)		
Adequate	Standard	42	82 (116)	0.720	0.069
	Intervention	39	74 (110)		

[a] Effect size $=(|\mu_1 - \mu_2|)/\sigma$, where σ is the common standard deviation. For these computations, the higher of the two standard deviations was used as the common standard deviation.

142 ± 126 days, median 114 days. Overall, the number of DWM in the six months following enrollment was similar for the control and the intervention groups (intervention group, $n = 67$, DWM = 63 ± 198; standard care group, $n = 60$, DWM = 65 ± 198; $p = 0.708$). The response to the intervention, however, varied according to literacy level. Subjects in the intervention group with inadequate literacy experienced 41 fewer DWM over the study period than subjects with inadequate health literacy in the control group (Table 2).

Comparing the ratio of the number of days that medication was available to the number of days that medication was required or medication possession ratio (MPR), the MPR was similar for the standard care and intervention groups (intervention group MPR 0.779 ± 0.335; control group MPR 0.779 ± 0.316; $p = 0.992$). Within subgroups of literacy skills, MPR did not differ between the intervention and control groups for subjects with inadequate ($p = 0.187$), marginal ($p = 0.649$), or adequate ($p = 0.675$) health literacy skills.

Subjects with inadequate or marginal health literacy skills were more likely to report the presence of a physical disability which made proper drop instillation more difficult ($p = 0.020$). Decreasing health literacy skills were associated with decreasing self-reported satisfaction with care (slope = 0.017, standard error = 0.005, $p = 0.002$). Subjects who scored in the marginal health literacy category were 2.5 times more likely to be satisfied with their disease management than those who scored in the inadequate health literacy category.

4. Discussion and conclusion

For each literacy level, the number of days without medicine was fewer in the intervention than in the control group, and the magnitude of the difference increased as literacy decreased. Subjects with lower health literacy levels who received literacy-level appropriate education experienced on average more than 30 days less without glaucoma medication than the less literate subjects who received standard. No such difference was noted in the subjects with higher literacy who received the educational intervention as compared to those more literate subjects who received standard care. In a similar study of patients with poorly controlled diabetes, investigators also found that a literacy-level appropriate intervention was only effective for the less literate subjects, resulting in improved disease management in this group [25]. Multiple factors including dosing schedule [30] and learning style [15] have been shown to be associated with glaucoma medication adherence, and perhaps factors other than health literacy are more influential in determining medication adherence patterns in those patients with greater understanding of written and verbal information. The finding that glaucoma medication adherence can be improved in less literate subjects is, however, encouraging that outcomes might also be improved in this vulnerable population.

The majority of the subjects in the study scored in the "adequate" health literacy range according to the health literacy assessment tool utilized, the ToFHLA. In previous work, we found that glaucoma patients in a similar age range in a University practice demonstrated lower health literacy skills than the subjects in this study, although the literacy assessment tool used in the previous study was not the ToFHLA but the Rapid Estimate of Adult Literacy in Medicine (REALM) [17]. Unlike the REALM, the ToFHLA includes numeracy assessment. The ToFHLA was chosen for this study in order to gain insight into patient' skills with the numerical concepts involved in glaucoma self-management, including the number of drops per day and laterality of treatment. Using the ToFHLA in this study, few subjects fell into the lower literacy categories and the difference in medication adherence between the intervention and standard care groups was not statistically significant. Given the data from this study, we estimate that 97 subjects with inadequate health literacy in each arm of the

study would have been needed to detect a significant difference in the number of days without medicine, with 80% power and assuming an alpha of 0.05 and two-sided test of significance.

Selection bias may have contributed to the lower numbers of subjects with poor health literacy enrolled in this study. Although every attempt was made to enroll consecutive subjects, those who declined to participate may represent a less literate group. No subjects were excluded because of poor cognitive function as tested by the MMSE, although based on epidemiological data of cognitive function in adults aged greater than 40 years, one would expect at least one subject to have scored lower on this test of cognitive ability [31]. This suggests that subjects with less cognitive ability may have declined participation. Additionally, less literate subjects may have declined participation due to embarrassment over the content matter. As the study was conducted in a VA eye clinic, the subject population is also biased in that it is predominantly male and may not represent a more diverse population of glaucoma patients.

Because poor medication adherence is a multidimensional problem, the intervention was designed to address more than one barrier to adherence. The video and print materials described the potential consequences of glaucoma, educating subjects about the risk of blindness. The study coordinator demonstrated eye drop instillation and asked the subjects to demonstrate their preferred technique, providing suggestions if instillation was unsuccessful. Subjects also received a monthly phone call, serving as a reminder and an opportunity to address problems with eye drops. The intervention, however, was not pilot-tested nor refined with feedback from patients, an important step to consider in future work. Additionally, in a larger study, it would be informative to tease out the differential effect of various components of such an intervention.

Although the comprehensive quantification of glaucoma medication adherence is inherently problematic, a strength of this study is the use of the closed pharmacy system within the VA Medical Center. Using pharmacy refill rates as a surrogate measure of medication adherence is confounded if a subject obtains medication from multiple pharmacies. Previous work has shown that veterans who receive care in the VA obtain almost all of their prescription medications through the VA pharmacy [32,33]. The clinic in which the study was conducted does not provide samples, reducing the influence of another potential confounder to appropriate quantification of medication adherence. In this pharmacy system, patients request refill medication by calling the pharmacy or mailing in a refill slip; as such, the refill data presented represent refills requested by the patient or a caregiver. Although it is possible that subjects received a prescription from a non-VA provider, at the time of this study, the most commonly prescribed class of glaucoma medications, the prostaglandin analogs, were not available as generic medications. Accordingly, for most subjects, the cost of a prescription outside of the VA would be more than 10 times the cost of the medication from the VA pharmacy.

Although the use of a closed pharmacy system and absence of available samples reduces confounders in the pharmacy refill records, this methodology does not address whether or not the patient successfully administered the drop (or if the drop was administered into the correct eye in cases for unilateral disease) and others have shown that many patients with glaucoma are not able to properly instill medication into the eye [34]. In our study, subjects with lower literacy were more likely to report a physical disability that interfered with drop instillation, but the sample was not large enough to test for an interaction between disability and literacy. One can imagine that a patient who has a disability such as arthritis or tremor impeding drop instillation might inadvertently waste drops and run out of medication prior to the expected refill date. Accordingly, in future work, we are directly observing and rating eye drop instillation techniques.

This study did not assess if medication nonadherence was intentional or nonintentional. Eye drops used to treat glaucoma have unpleasant side effects for some patients, including burning, visual blurring, and ocular redness. We did not assess if subjects forgot to use drops or stopped taking the drops due to side effects or other reasons. Research using multifaceted measures of adherence, including self-report, medication monitors, and direct observation could shed light on this complex problem.

Many studies of glaucoma medication adherence using refill rates assume bilateral administration, which may lead to underestimation of adherence in subjects for whom medication is only prescribed for one eye. In this sample of glaucoma patients, we found that more than 10% of subjects were prescribed medication for only one eye and accounted for this in the calculations of quantity of medication required. Although we considered the complexity of the glaucoma medication regimen, we did not take into account co-morbid medical conditions or non-glaucoma prescription medications, which may also contribute to glaucoma medication nonadherence. Future work should consider the overall complexity of the patient's medication regimen and the contribution of concurrent diseases to adherence.

To our knowledge, this is the first study to address both health literacy and patient satisfaction with glaucoma management and we found that the least literate subjects were 2.5 times less likely to be satisfied with their disease management than subjects who demonstrated greater health literacy skills. Whether this dissatisfaction represents flaws in the care provided or the perception of appropriate management or a combination of both has yet to be explored.

Although health literacy and educational attainment are closely related, the terms do not represent synonymous concepts. Health literacy encompasses a variety of experiences and personal resources related to healthcare and may change over time. Indeed, declining health literacy is associated with increasing age, even when controlling for cognitive status [35]. As such, health literacy is more closely related to health outcomes including mortality than is educational attainment [23].

4.1. Practice applications

The number of Americans confronted with both poor health literacy and glaucoma is expected to increase substantially in the near future. Over the next 20–25 years, the number of Americans over the age of 65 years is projected to grow by 13–20% [36]. The number of Americans with glaucoma is expected to increase by 50% in the next fifteen years [3]. Due to changing demographics and an economy in flux, the proportion of Americans with poor health literacy skills is projected to increase substantially over the next 20 years [37]. Focusing future research and educational efforts on the problem of low health literacy concentrates efforts on the most vulnerable glaucoma patients.

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(c) Contributions of authors: Design of the study (KM, PL, RA), Data collection (KM, AV, AE), Interpretation of the data (KM, PL, SS), Review of the manuscript (KM, PL, SS, AV, AE).
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